Chapter XVI: Protocol Management

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Protocol Consent Form Management in CRIS

This chapter summarizes how to document the assignment of a patient to a protocol and the process for forwarding signed protocol consent documentation to the Medical Record Department (MRD). This process impacts all end-users of the CRIS system, as well as staff who have previously completed the NIH/MIS Form 54.

The signature page of the completed protocol consent document (Form 2514-1) must be faxed to the MRD at 301 480-3126 upon completion. The original signed protocol consent document must be filed in the inpatient chart for inpatient admissions and forwarded to the MRD for outpatients for filing in the permanent medical record.

Original protocol consent documents must be printed from the clinical research studies website at the following URL: http://www.cc.nih.gov/protocolconsents/

Definition of Terms

Form 54/ATV Form – The Form 54 for requesting admissions, travel and vouchers has been replaced by the Admissions, Travel and Voucher System also known as ATV. The ATV system can be found at http://atv.cc.nih.gov. For additional information about the ATV system, contact admissions at 301 496-3141.

Primary Protocol – The primary reason for the patient visit to the Clinical Center. All orders entered into CRIS will be attributed to this primary protocol unless they are included in a protocol order set. The primary protocol in CRIS will be identified as the **Visit Reason**.

Secondary Protocol – Ancillary protocols specific to a patient visit or spanning multiple visits. Orders entered in CRIS will not be attributed to secondary protocols unless there is an active protocol order set established for that particular protocol.

Active Protocol – a protocol in which a patient is actively participating.

Active Protocol Status Designations

- Unconfirmed – patient assigned to a protocol, but the Medical Record Department has not received either a faxed copy of the signature page of a valid, signed protocol consent form (NIH-2514-1) and/or the original, valid protocol consent document.

- Confirmed – the Medical Record Department has received a faxed copy of the signature page of a valid, signed protocol consent form and/or the original, valid protocol consent document.
- Exemption – patient assigned to designated exemption protocol, or remains on a treatment protocol as a "single patient single use" exemption

Inactive Protocol – a protocol in which a patient is no longer participating or the study has ended.

Inactive Protocol Status Designations

- Removed – an *individual* patient is removed from a protocol because they no long qualify to participate in the study, because they have completed the protocol, or because they have elected to withdraw from the study.
- Error – the protocol was assigned in error.
- Terminated – protocol completed or ended (e.g. end of study) and *all* patients are removed from the protocol.

Visit Reason – a term in CRIS identifying the primary protocol in the **Health Issues** section on the **Patient Info** tab and **Summary** tab.

Protocol Order Set – a group of orders related to a specific protocol.

Onset Date – indicates the actual date the protocol consent document was signed.

Entered Date – indicates the date that the consent status was entered and/or updated in the CRIS **Health Issues** section of the **Patient Info** tab.

Process Description

Register and Place a New Patient on a Primary Protocol

1. Complete a Form 54 – now known as an Admissions, Travel and Voucher Request (ATV). This form can be found at http://atv.cc.nih.gov
2. Electronically submit the ATV form to admissions.
3. Admissions will register the patient, assign a medical record number and document the patient's primary protocol number. The primary protocol will display in the CRIS header information for the patient, and under visit reason in the CRIS **Health Issues** section of the **Patient Info** tab.
4. Obtain all required signatures on the last page of the protocol informed consent document (NIH-2514-1)

5. Fax the last page (signature page) of the protocol informed consent to Medical Records at 301-480-3126 as soon as all of the signatures have been obtained.
6. Inpatient Status: File the original protocol consent document in the inpatient chart.
   Outpatient status: Forward the original protocol consent document to the MRD for filing in the permanent medical record.
7. The MRD will update the protocol status and confirm receipt of the consent document in the CRIS under the **Health Issues** section of the **Patient Info** tab no later than the next business day.
8. For subsequent visits, submit a **Change Protocol Assignment** service requisition in CRIS to request a change to a primary protocol.

NOTE: *This will only change the primary protocol for the specified patient. Complete all necessary fields in the CRIS order worksheet including the disposition of the previous primary protocol. To* ***inactivate*** *an existing protocol patient assignment, refer to the section below on* ***Inactive Protocols.***

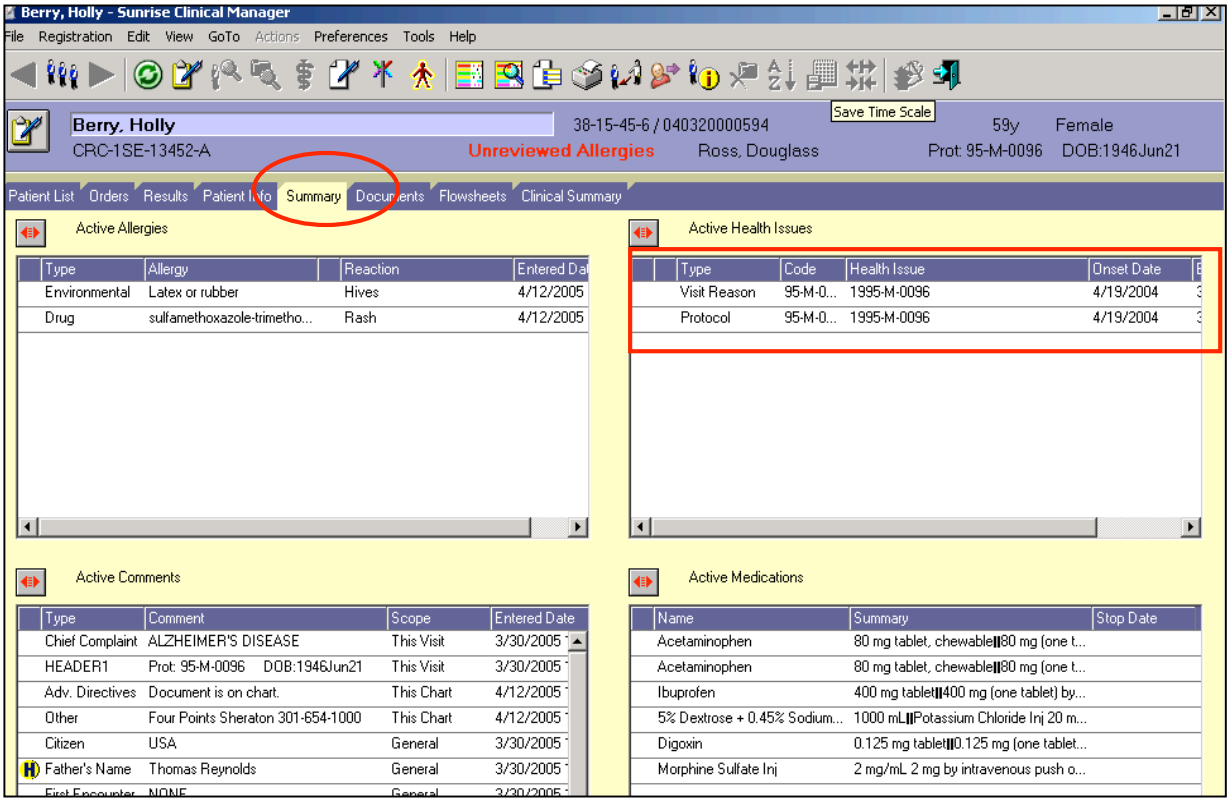
Place a Patient on a Secondary Protocol

1. Complete all required signatures on the last page of the protocol informed consent document (NIH-2514-1)
2. Fax the last page (signature page) of the protocol informed consent to the Medical Record Department at 301-480-3126 as soon as all of the signatures have been obtained.
3. Inpatient status: File the original protocol consent form in the in patient chart.
   Outpatient status: Forward the original consent document to the MRD for filing in the permanent medical record.
4. The MRD will update the protocol status and confirm receipt of the faxed signature page of the protocol consent document in the CRIS **Health Issues** section of the **Patient Info** tab.

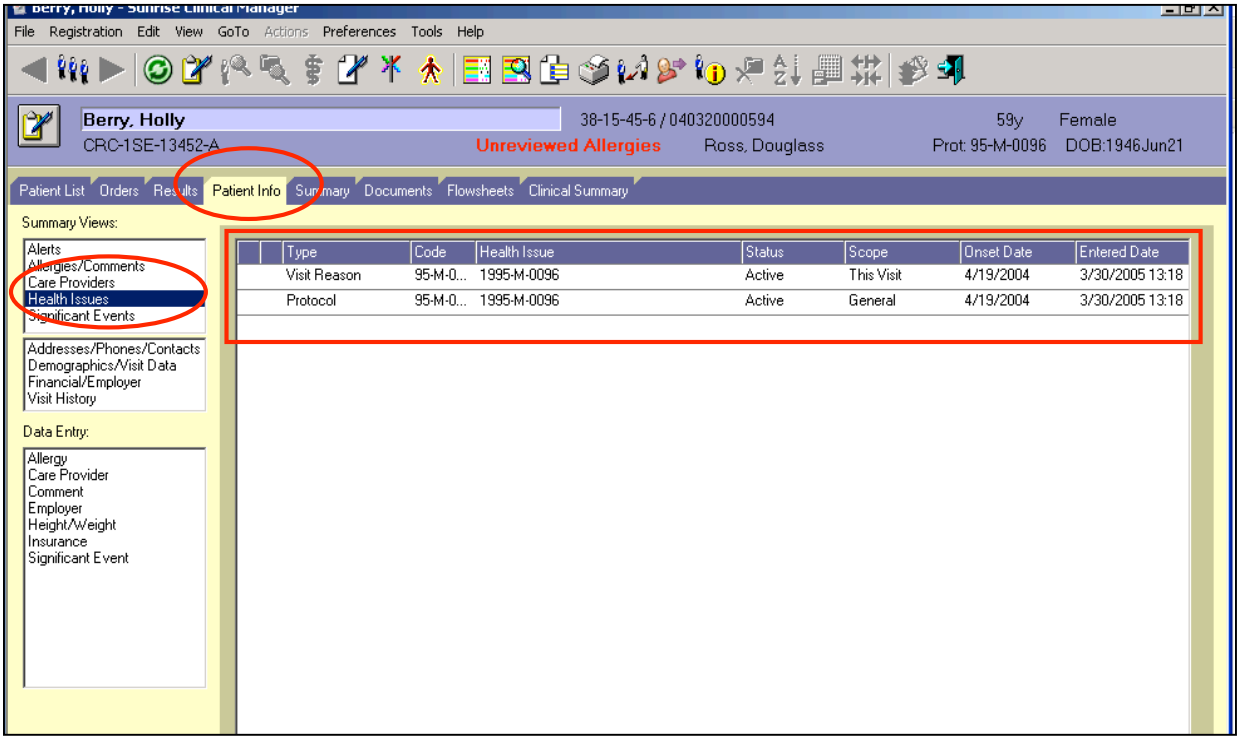
Protocol and Consent Information in CRIS

View Protocol Information, Protocol Status and Consent Form Management in CRIS

1. Select a patient from the patient list.
2. Protocol information can be viewed on the **Summary tab** under **Active Health Issues**.
3. Or the same information can be viewed under the **Patient Info** tab by selecting the **Health Issues** view.



Screen 16.1: Sample View of Summary Tab



Screen 16. 2: Sample View of Patient Info Tab

Explanation of Terms on the Health Issues Screen

Type:

Visit Reason – represents the primary protocol. The primary protocol is the reason for the patient visit to the Clinical Center. All orders entered into CRIS will be attributed to this primary protocol unless they are included in a specific protocol order set.

Protocol – represents all other patient protocols, either active or inactive

Health Issues: Lists the protocol number.

Status: Designates the status of a protocol for a specific patient.

Active Protocol – a protocol in which a patient is actively participating

Active Protocol Status Designations

- Unconfirmed – patient assigned to a protocol in CRIS, but the Medical Record Department has not received the faxed copy of the signature page from a valid, signed protocol consent form (NIH-2514-1)
- Confirmed – the Medical Record Department has received the faxed copy of the signature page from a valid, signed protocol consent form
- Exemption – will be noted as specific type of exemption by the number assigned:
    - Single Patient Single Use – retains treatment protocol number but protocol status will be noted as "Exemption"
    - Emergency Use IND – Special Exemption Number will be assigned and entered by Medical Records as the Primary Protocol (YR-IC-9980 number)
    - Treatment IND – Special Exemption Number will be assigned and entered by Medical Records as the Primary Protocol (YR-IC-9990 number)

Inactive Protocol – a protocol in which a patient is no longer participating

Inactive Protocol Status Designations

- Removed – an *individual* patient is removed from a protocol because they no long qualify to participate in the study, because they have completed the protocol, or because they have elected to withdraw from the study.
- Error – the protocol was assigned in error.
- Terminated – protocol completed or ended (end of study) and *all* patients are removed from the protocol.

Scope: Indicates **This Visit** for the primary protocol, and **General** for all other protocols.

Onset Date: Actual date that protocol consent form was signed.

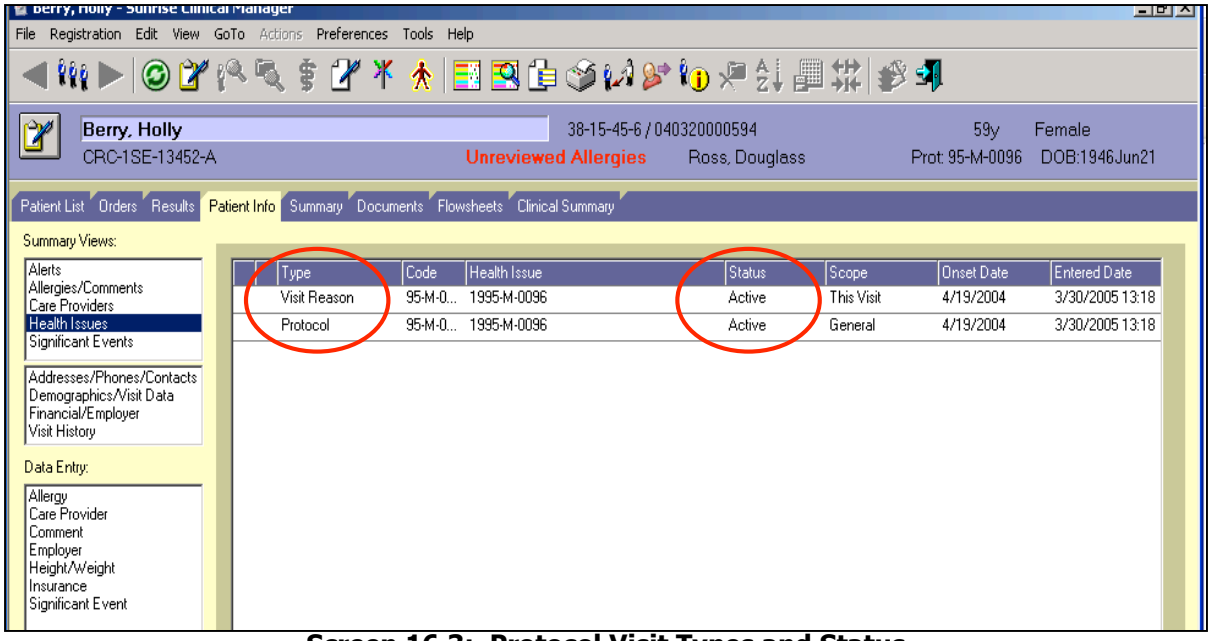
Entered Date: Indicates the date that the consent status was entered and/or updated in the CRIS **Health Issues** section of the **Patient Info** tab.

CRIS Documentation of Protocol and Consent Status

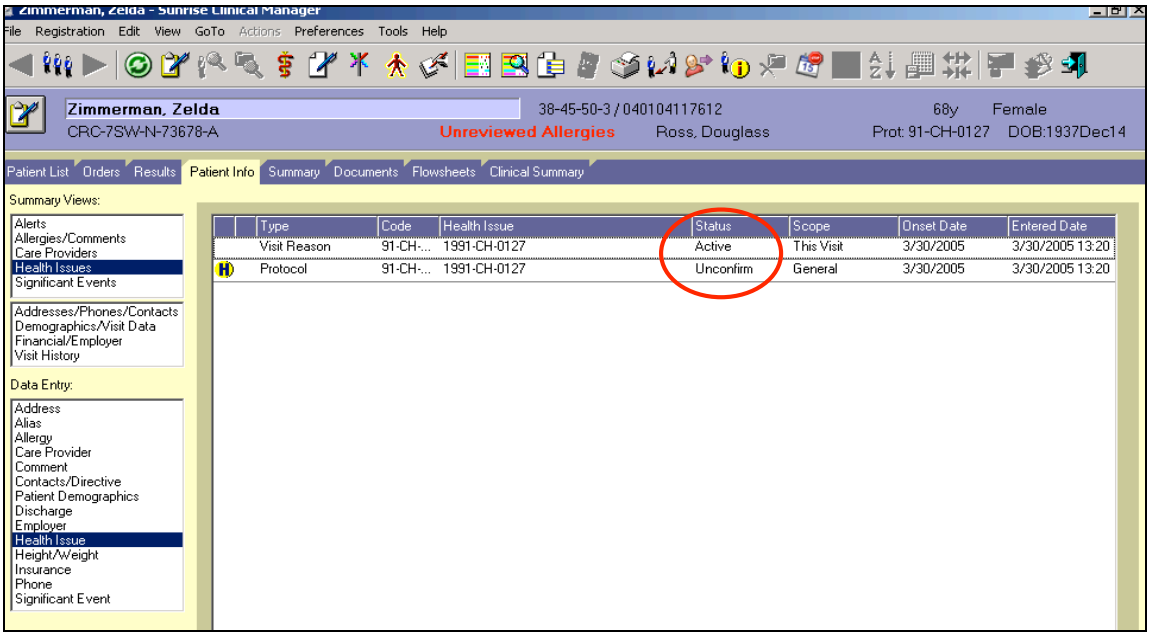
Primary Protocols

A protocol is posted in CRIS when admissions has registered the patient and assigned a patient to a protocol according to the information submitted via the ATV form and or updates are requested via the **Change Protocol Assignment** service requisition in CRIS. The primary protocol is posted twice in CRIS – the **Visit Reason** designates the primary protocol. The **Protocol** will document the consent status.

Prior to the receipt of the faxed copy of the signature page of a valid, signed protocol consent form and/or the original, valid protocol consent document, the MRD will update the protocol status from **Active** to **Unconfirmed** for the protocol.

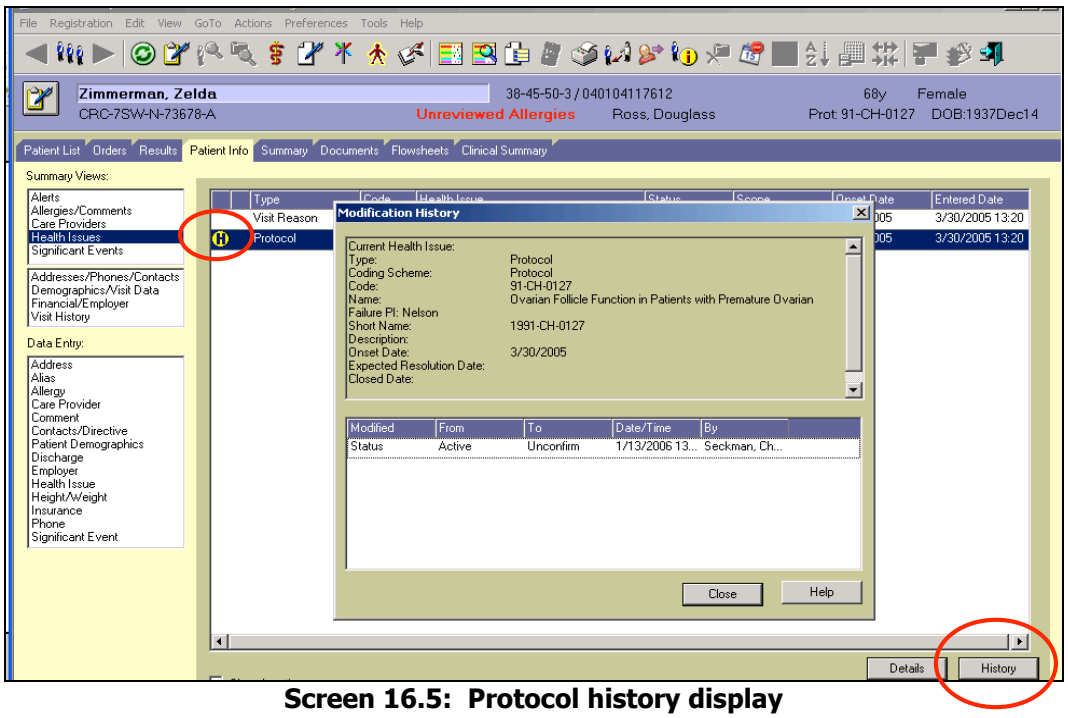


Screen 16.3: Protocol Visit Types and Status



Screen 16.4: Change in Status from active to unconfirmed

Note the yellow (H) next to the protocol. When highlighting a protocol with this (H) icon, the **History** button at the bottom of the screen becomes active. Selecting the **History** button will display information about the protocol and an audit trail of changes in consent status will appear.

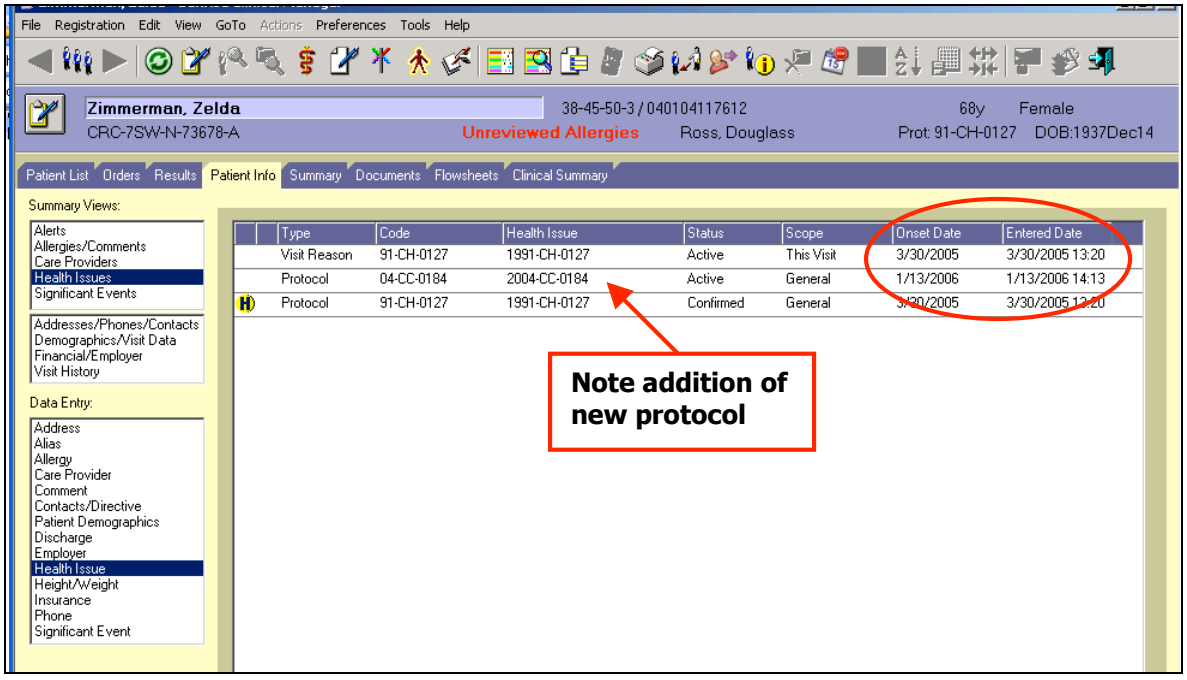


Screen 16.5: Protocol history display

Place a Patient on a Secondary Protocol

1. Complete all required signatures and dates on the last page of the protocol informed consent document (NIH-2514-1)
2. Fax the last page (signature page) of the protocol informed consent to the Medical Record Department at 301 480-3126 as soon as all of the signatures have been obtained.
3. Inpatient status: File the original protocol consent form in the inpatient chart.
   Outpatient status: Forward the original consent document to the MRD for filing in the permanent medical record.
4. MRD will update the protocol status and confirm receipt of the faxed signature page of the protocol consent document in the CRIS **Health Issues** section of the **Patient Info** tab.

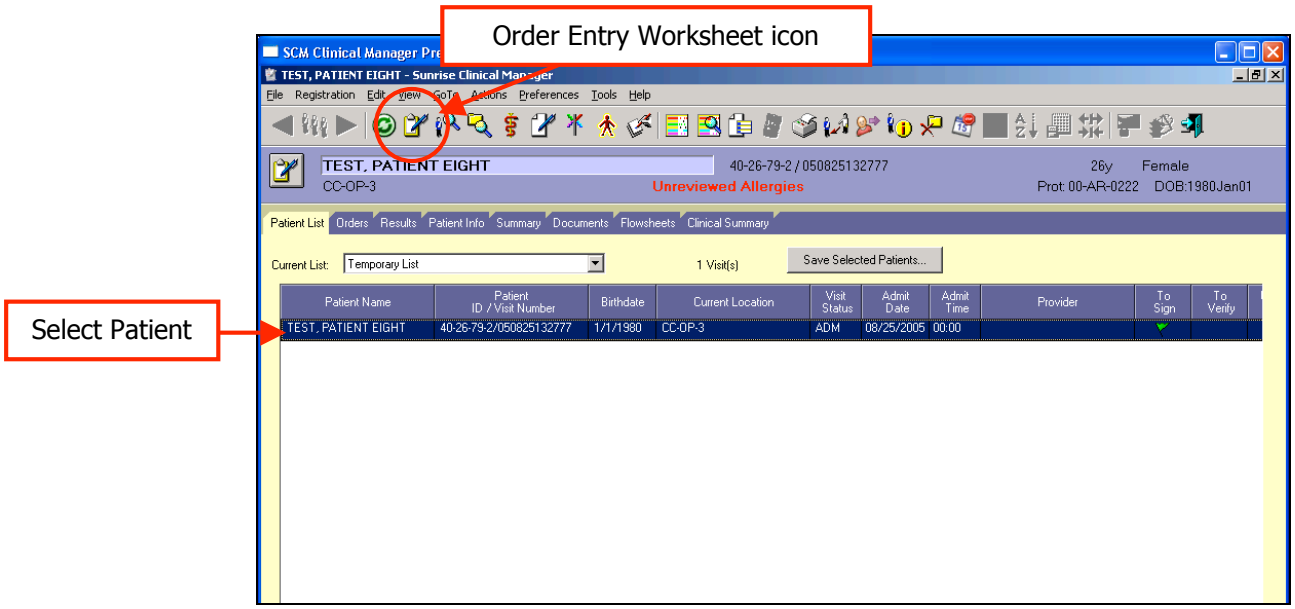
The **Onset Date** indicates the actual date the protocol consent was signed. The **Entered Date** indicates the date that the Medical Record Department entered the consent data into CRIS verifying the receipt of the faxed copy of the protocol consent signature page.



Screen 16.6: Onset and Entered Date

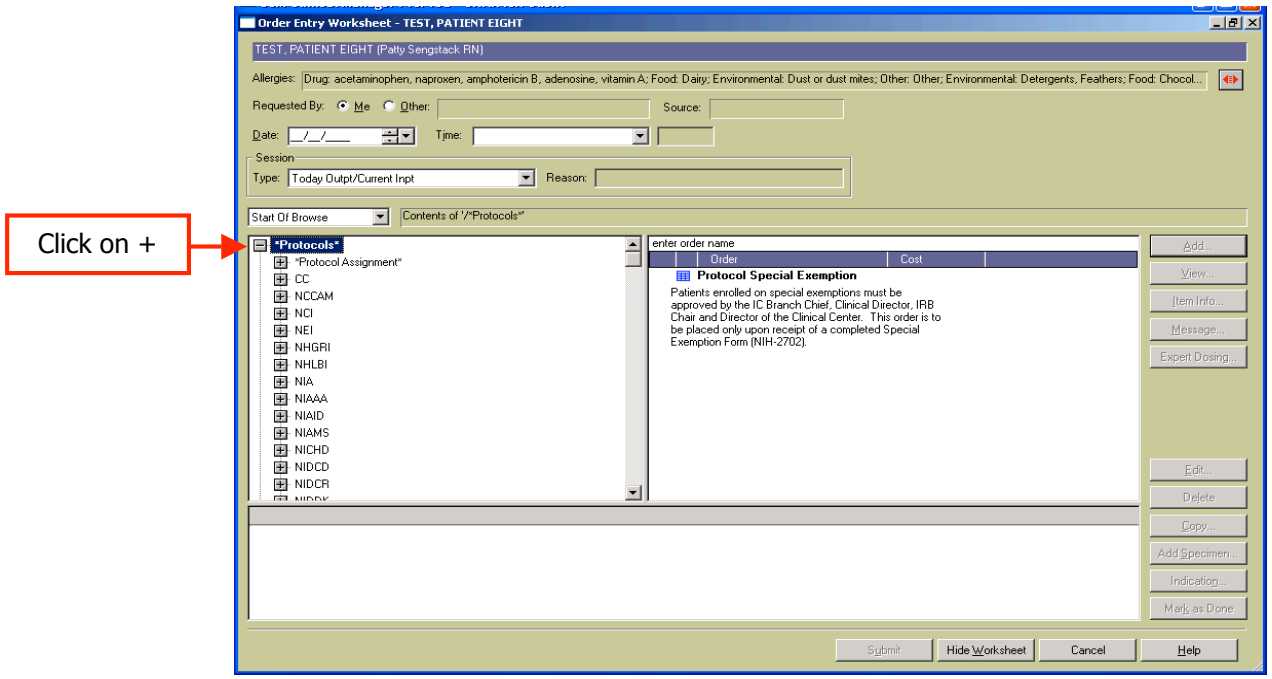
Request a Change in a Patient's Protocol Assignment

1. Search for and select your patient in CRIS.
2. Click on the **Order Entry Worksheet** icon.



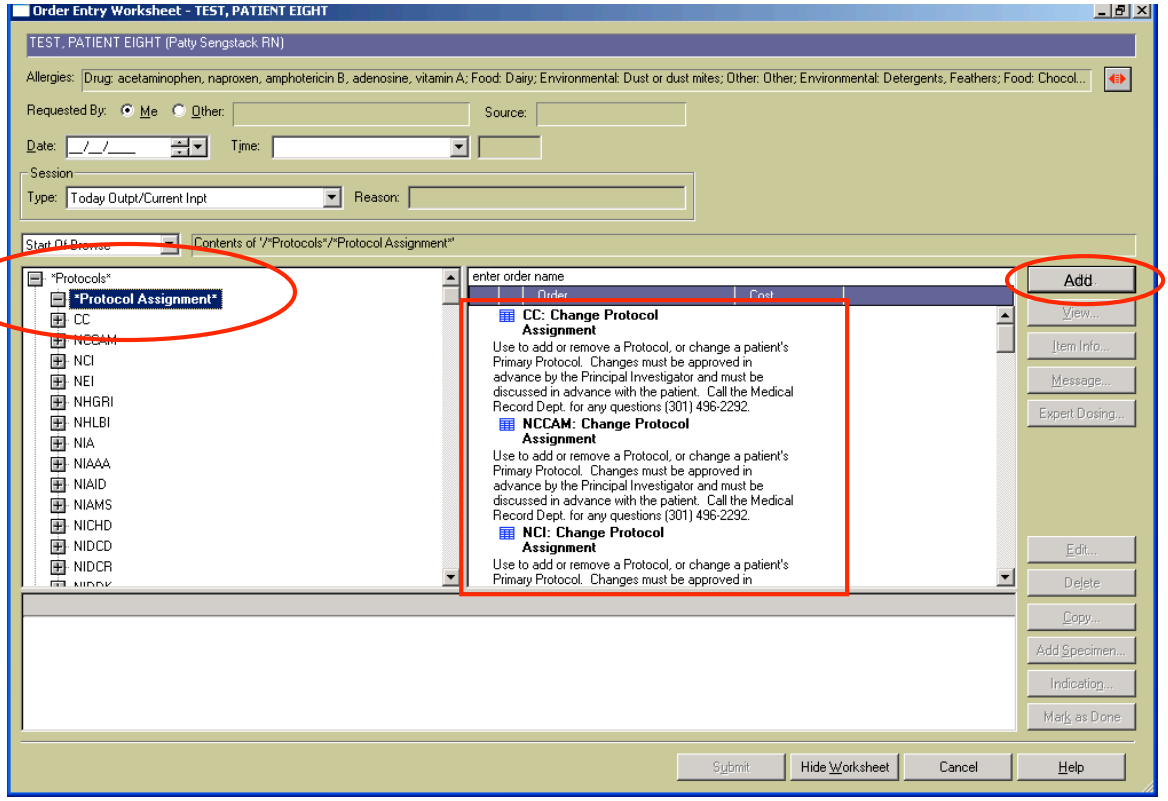
Screen 16.7: Enter Order icon

3. Expand the **Protocols** order list by clicking on the **+**.



Screen 16.8 : Order Entry Worksheet

4. Select **Protocol Assignment**
5. Select the appropriate **Change Protocol Assignment order** from the list on the right. Choose based on CC or a specific institute.
6. Select **Add**.



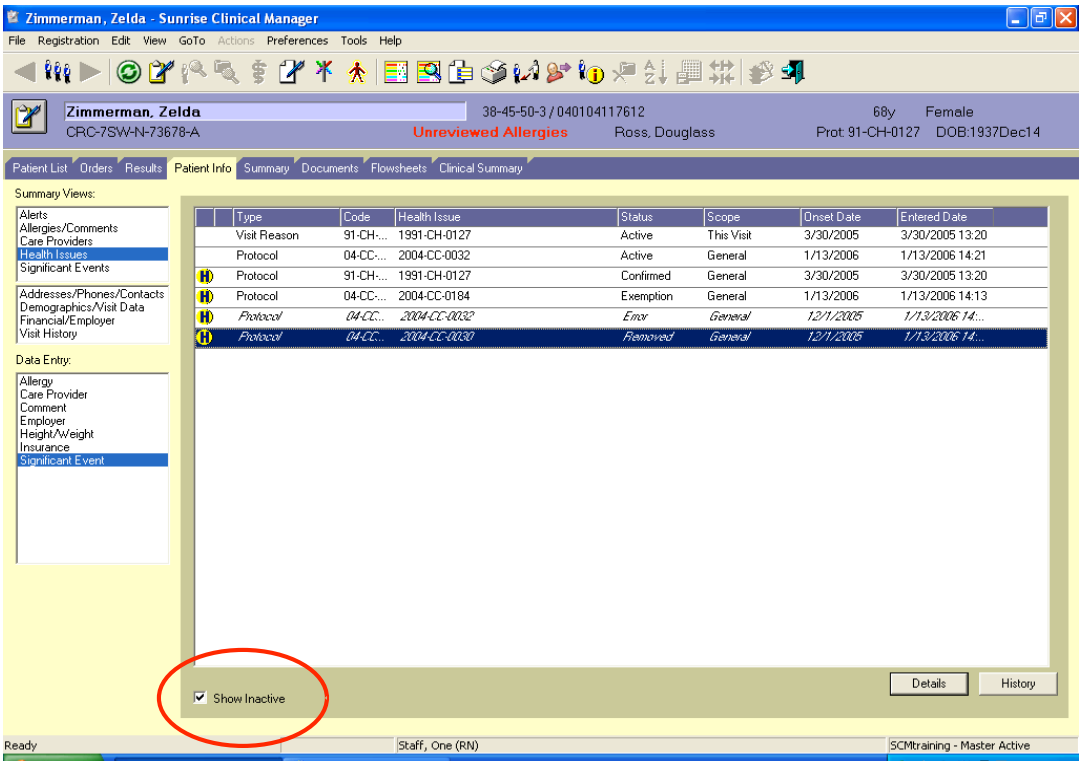
Screen 16.9 : Change Protocol Assignment Order

7. The **Order Entry Worksheet** window will open. Complete the fields as necessary. These orders may be utilized to request one or multiple actions from the following:
   - remove a patient from a protocol
   - add a patient to a protocol
   - change the primary protocol (when selecting this action, the user must identify the disposition of the previous primary protocol – i.e. maintain as a secondary protocol or removing the patient).
8. Select **OK.**
9. Select **Submit**.
10. The submitted order will generate a service requisition in the Medical Records Department for processing. Service requisitions are completed no later than 24 hours from submission.

Please contact Tricia Coffey or Debby Roszell (301-496-2292) with questions.

View Inactive Protocols

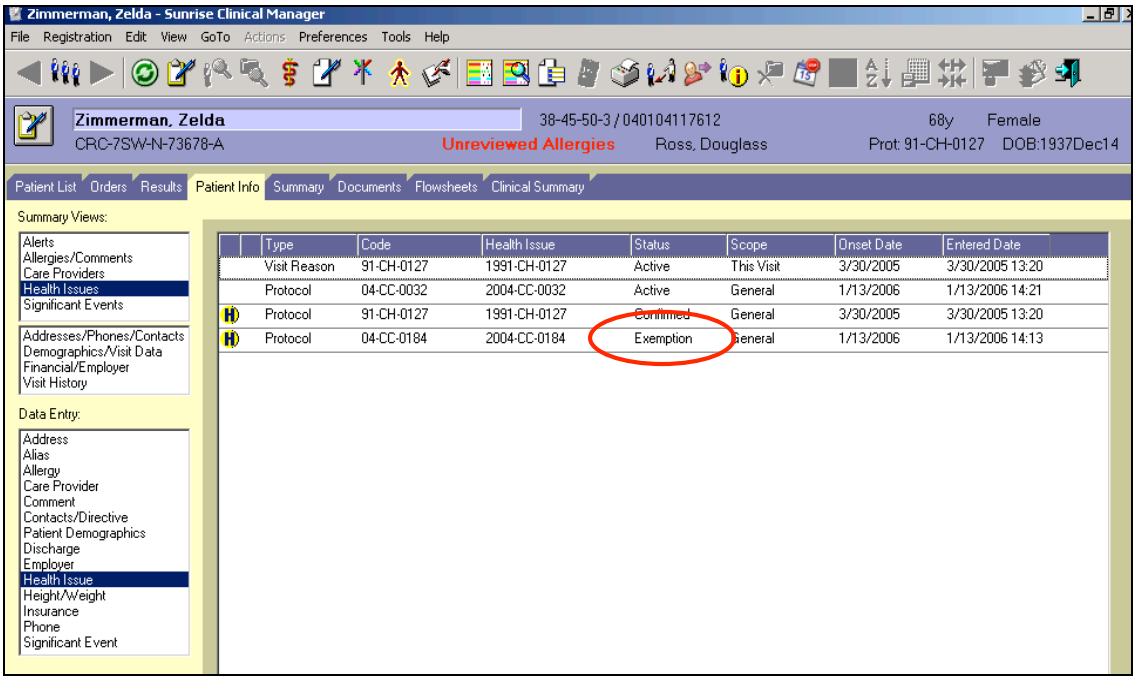
Check the **Show Inactive** box at the bottom left of the **Patient Info** screen. Inactive protocols will be added to the display in *italics.* Note that the history is retained for inactive protocols as indicated by the yellow (H) icon.



Screen 16.10: Show Inactive Status

Place a Patient on a Protocol Special Exemption

The process for placing a patient on a protocol exemption is described in the M93-1 MAS policy on the Structure and Process of Research Involving Human Subjects at the Clinical Center http://internal.cc.nih.gov/policies/PDF/M93-1.pdf Patients enrolled on special exemptions must be approved by the IC Branch Chief, Clinical Director, IRB Chair and Director of the Clinical Center using the Special Exemption Form (NIH-2702) http://intranet.cc.nih.gov/medicalrecords/forms/pdf/NIH-2702.pdf Once the paper form is completed Medical Records will post the protocol status in CRIS in the **Health Issues** section of the **Patient Info** tab.



Screen 16.11: Exemption Status

Protocol and Consent Status Reports

To ensure validity and accuracy of the data on protocols and consent status in CRIS, each Institute will receive end-of-month reports. Reports will be by protocol and will be provided to the Principal Investigator or their designee. Ad hoc reports will be available by request. For additional information on these reports, please call the **Medical Record Department at 301 496-2292.**